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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,228	06/21/2005	Ernest Loumaye	KZI-001US	1620

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EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	**PAPER NUMBER**
1654	
MAIL DATE	**DELIVERY MODE**
08/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,228	LOUMAYE, ERNEST	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *73-102* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEGDMENT TO THE PRELIMINARY AMENDMENT AND THE STATUS OF THE CLAIMS

The preliminary amendment filed 06/21/05 is acknowledged, entered and considered. In view of Applicant's request claims 1-72 have been canceled and claims 73-102 have been added. Claims 73-102 are active and pending in the application.

ELECTION/RESTRICTION

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 73-101, drawn to a method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a gonadotrophin releasing hormone (GnRH) agonist.

Group II, claim(s) 102, drawn to a kit for the treatment of infertility in female mammals comprising a pharmaceutical agent comprising a (GnRH) agonist and at least one additional agents.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: The method as claimed in Group I can be practiced by another different apparatus or by hand or the apparatus (the kit) as claimed can be used to practice anther and materially different processes. (MPEP § 806.05(e)). The method of Group I can be practiced by another materially different apparatus such as the use or employment of implant, or inhalation or transdermally or manually by using a syringe for injection or other surgical means. There is no Unity of Invention between the methods of administration of Group I to treat infertility by intra-nasal, oral, sub-cutaneous, intramuscular, vaginal, rectal, transdermal and pulmonary route of administration and the kit formulation of Group II intended for the treatment of infertility. Thus, the processes as recited above don not correspond to the same technical features and are not connected in design, operation or effect because they differ in method steps, parameters and reagents used, and as such, the methods as grouped are independent and distinct, each from the other because they represent different technical features and different inventive endeavors. Therefore, Groups I and II does not share the same technical features, the inventions do not relate to the same inventive concept.

ELECTION OF SPECIES

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species I is drawn to a GnRH agonist listed in claim 78.

If Applicant elects a synthetic peptide agonist of GnRH from Species I, Applicant must further elect the synthetic peptides listed in claim 79. If busereline elected as a synthetic peptide claims 80 and 96-101 will be examined along the elected busereline.

Species II is drawn to a physiologically active protein, which is granulocyte colony-stimulating factor (G-CSF), claim 5.

Species II is drawn to pharmaceutical agents listed in claims 82, 90 and 93.

If Applicant elects selective estrogen receptors modulators (SERM) from Species II listed in claim 90, Applicant must further elect the SERM listed in claim 91. Similarly, if Applicant elects aromatases inhibitors from Species II listed in claim 90, Applicant must further elect the aromatase inhibitors listed in claim 92.

Species III is drawn to cytokines listed in claim 84 and includes claim 83.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species I-III are related as independent injectable pharmaceutical formulations comprising GnRH agonist containing different physiologically active proteins as active ingredients in which Species I, II and III are different formulations wherein the physiological active proteins in Species I is GnRH agonist, and in Species II is pharmaceutical agent in combination with luteal support agent or stimulating follicular growth agent or triggering final follicular maturation and ovulation agent while in Species III is cytokine agent.

The following claim(s) are generic: claims 73-77, 81, 85-89 and 95.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Species I-III (i.e., the three physiological active proteins, namely GnRH agonist, pharmaceutical agent and cytokine) do not correspond to the same technical feature and are not connected in design, operation or effect because they differ in structure and formulation, and as such, the physiological active proteins as grouped are different from each other because they represent different technical features and different inventive endeavors. Hence, the physiological active protein formulations have different structures, functions and different effects. Thus, the species require different patent and literature search and a reference teaching the physiological active protein of GnRH agonist (Species I) will not teach the physiological active protein of pharmaceutical agents (Species II) or cytokines

(Species III) and *vice versa*. Therefore, Species I, II and III do not share the same technical features, the inventions do not relate to a single inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

CONCLUSION AND FUTURE CORRESPONDANCE

Claims 73-102 are subject to restriction and/or species election requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AAM/ Mohamed/AAM
August 23, 2007

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600